New Regulations

FDA is currently developing regulations on the following major provisions of the Bioterrorism Act. Except for the specified exemptions, these new regulations will apply to all facilities for all foods and animal feed products regulated by FDA, including dietary supplements, infant formula, beverages (including alcoholic beverages) and food additives. FDA regulates all foods except meat, poultry and processed egg products which are regulated by the U.S. Department of Agriculture.

- ***Registration of Food Facilities***—Domestic or foreign facilities that manufacture, process, pack or hold food for consumption in the U.S. must register with the FDA no later than **December 12, 2003**. Registration will consist of providing information, including firm name, address, etc. Farms, restaurants, retail food establishments, non-profit establishments that prepare or serve food, and fishing vessels not engaged in processing are exempt from this requirement. Also exempt are foreign facilities if the food from the facility is to undergo further processing or packaging by another facility before it is exported to the U.S. or if the facility performs a minimal activity such as putting on a label. FDA must issue final regulations no later than December 12, 2003, but facilities must register by this date even if the regulations are not finalized. There is no fee associated with registration.

- ***Establishment and Maintenance of Records***—Businesses that manufacture, process, pack, transport, distribute, receive, hold or import food will be required to create and maintain records that FDA determines are necessary to identify the immediate previous sources and the immediate subsequent recipients of food (i.e., where it came from and who received it). This would allow FDA to follow up on credible threats of serious adverse health consequences or death to humans or animals by tracing the food back to its source. Farms and restaurants are exempt from this requirement. FDA must issue final regulations by December 12, 2003.

- ***Prior Notice of Imported Food Shipments***—On or after December 12, 2003, FDA must receive advance notice of each shipment of food into the U.S. The notice must include a description of the article, the manufacturer and shipper, the grower (if known), the country of origin, the country from which the article is shipped, and the anticipated port of entry. FDA must issue the final regulation by December 12, 2003. If the regulation is not final by that date, the Act still requires importers to provide notice to FDA no less than 8 hours and no more than 5 days prior to shipment until the regulation takes effect.

- ***Administrative Detention***—Authorizes FDA to administratively detain food if the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. The Act requires FDA to issue regulations to expedite procedures for perishable foods, but does not specify a deadline.

New Guidance

The Bioterrorism Act includes several provisions for which FDA is currently working on guidance. These FDA guidance documents will specify the procedures to be followed by FDA field offices in carrying out these provisions. Some of the provisions requiring guidance on which FDA is currently working are:

Debarment—Authorizes FDA to debar (prohibit from importing food) any persons who have been convicted of a felony relating to the importation of any food or who have engaged in a pattern of importing adulterated food that presents a threat of serious adverse health consequences or death to humans or animals. Food imported by a debarred person or with the assistance of a debarred person will be held at the port of entry into the U.S. Food so held may be delivered to non-debarred persons who demonstrate—at their expense—that the food is in compliance with FDA standards.

Marking—The Secretary may require marking (labeling) of foods refused admission into the U.S. Marking shall be at the owner's or consignee's expense.

Port Shopping—Food that has been refused admission into the U.S. may be considered adulterated if it is offered again for import, unless the person importing the food or offering it for import demonstrates that the food is now in compliance with FDA standards.

Import for Export—FDA has already announced the availability of guidance authorizing food additives, color additives or dietary supplements not otherwise permitted in the U.S to be imported only for use in a product that will be exported from the U.S. based on an importer's statement and posting of a bond. However, the Secretary may refuse admission if there is credible evidence that the submitted statement is not true.

Single copies of this document, *Regulatory Procedures Manual, Chapter 9, Subchapter Import for Export*, are available from the Division of Import Operations and Policy (HFC-170), Office of Regulatory Affairs, 5600 Fishers Lane, Rockville MD 20852. A copy can be obtained electronically at http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9impex.html.

Opportunities for Public Comment

Comments on New Regulations: FDA is currently accepting comments on Registration of Food Facilities (Docket Number 02N-0276) Establishment and Maintenance of Records (Docket Number 02N-0277) Prior Notice of Imported Food Shipments (Docket Number 02N-0278) and Administrative Detention (Docket Number 02N-0275) as the regulations are being developed. FDA expects to publish proposed regulations on these measures within the next six months, and will continue to seek public comment for at least 60 days after the regulations are proposed.

Comments on Guidance: FDA will accept comments at any time on guidance documents once they are published. FDA is currently receiving comments on the guidance document *Regulatory Procedures Manual, Chapter 9, Subchapter Import for Export (*Docket Number 02D-0402).

Written comments on the New Regulations and New Guidance can be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments can be sent electronically to www.fda.gov/dockets/ecomments. It is important to include the docket numbers when providing comments.

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

PROTECTING THE FOOD SUPPLY:

FDA Actions on New Bioterrorism Legislation

On June 12, President George W. Bush signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) which includes a large number of provisions to help ensure the safety of the U.S. from bioterrorism, including new authority for the Secretary of Health and Human Services (HHS) to take action to protect the nation's food supply against the threat of intentional contamination. The Food and Drug Administration (FDA), as the food regulatory arm of HHS, is responsible for developing and implementing these food safety measures, including four major regulations and several guidance documents. This brochure is intended to provide an overview of the food safety and security provisions of the law. Information about provisions of the Bioterrorism Act under FDA's jurisdiction and the agency's implementation plans is available at http://www.fda.gov/oc/bioterrorism/bioact.html.